

REMARKS

I. PRELIMINARY REMARKS

Minor modifications have been made to the specification. Claims 20, 24, 25 and 45 have been amended. Claims 66-68 have been added. Claim 23 has been canceled. Claims 1-21, 24-26, 43-48, 50-54 and 64-68 remain in the application. Claims 3, 6-10, 12-16 have been withdrawn from consideration. Reexamination and reconsideration of the application, as amended, are respectfully requested.

The Office Action indicates that claims 52-54 and 65 have been allowed. In view of the fact that claims 53 and 54 depend from rejected claim 47, it would appear that the Examiner intended to indicate that claims 53 and 54 have been "objected to" and would be allowable if rewritten in independent form. Applicant hereby requests that the Examiner clarify the status of claims 53 and 54 in the next Office Action if the rejection of claim 47 is maintained.

II. OBJECTION TO THE SPECIFICATION UNDER 37 C.F.R. § 1.75(D)(1)

The specification has been objected to under 37 C.F.R. § 1.75(d)(1) for purportedly failing to explicitly state what structure, material and acts perform the function recited in the mean-plus-function element in claim 64. Applicant respectfully submits that the objection has been obviated by the amendment above to the specification and should be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 102

A. The Rejection

Claims 1, 2, 4, 5, 11, 17-21, 23, 24-26, 43-48, 50, 51 and 64 have been rejected under 35 U.S.C. § 102 as being anticipated by the Webster patent (U.S. Patent No.

5,431,168). The rejection under 35 U.S.C. § 102 is respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Webster Patent

The Webster patent is directed to a steerable open lumen catheter 10 that includes proximal catheter body 12 and a tip portion 14. The tip portion 14 includes ring electrodes 15 and a tip electrode 19, which is mounted by means of a tubular insert 21 that extends into a lumen 18 of the catheter 10. The catheter 10 also includes lumens 20 and 22. [Note Figure 2.] The puller wire 36 passes through the lumen 20 and is attached to the tip electrode 19 by a weld 31, while the electrical lead wires 62 pass through lumen 22 and are connected to electrodes 15 and 19.

The Webster patent describes a number of configurations for the lumen 20. [Column 4, lines 10-67.] In one implementation, the lumen 20 includes a tightly wound coil spring 48 that extends through the lumen 20 in the proximal catheter body 12, but not into the tip portion 14, which instead includes a lubricious polytetrafluoroethylene (i.e. Teflon®) sleeve 38. The proximal and distal ends of the coil spring 48 are attached to the proximal catheter body 12 with glue 49. The puller wire 36 passes through the lumen defined by the coil spring 48 and the sleeve 38. Alternatively, the sleeve 38 may be eliminated and replaced by stretching a portion of the coil spring 48 so that a loosely wound distal portion 51 is located within the tip portion 14.¹ Here too, the tightly wound proximal portion 48 of the coil spring is attached to proximal and distal ends of the proximal catheter body 12 (not the tip portion 14) with the glue 49. The Webster patent does not indicate whether or not the loosely wound distal portion 51 is secured to anything. The puller wire 36 passes through the lumen defined by the proximal portion 48 and the distal portion 51.

¹ Although the text of the specification appears to state that there are two different springs 48 and 51, Figure 4 appears to show a single spring with two differently wound portions.

C. Discussion Concerning Claims 1, 4, 5, 11, 17-19 and 26

Independent claim 1 calls for a combination of elements comprising “an elongate body defining a proximal portion and a distal portion and ... the distal portion of the elongate body defining a proximal end and being more flexible than the proximal portion,” “a steering wire,” “**a stiffening member secured to the distal portion** of the elongate body, entirely located inward of the outer surface of the elongate body, and defining a proximal end that is substantially adjacent to the proximal end of the elongate body distal portion” and “a handle.” The combinations defined by claims 4, 5, 11, 17-19 and 26 include, *inter alia*, the elements recited in claim 1. The Webster patent fails to teach or suggest such combinations.

For example, with respect to independent claim 1, the Office Action has taken the position that the Webster steering wire sleeve 38 corresponds to the claimed “stiffening member.” [Office Action at pages 3 and 4.] In contrast to the invention defined by claim 1, and assuming for the sake of argument that the Webster tip portion 14 corresponds to the claimed “distal portion,” there is nothing in the Webster patent which indicates that the sleeve 38 is secured to the tip portion 14. Referring to Figure 1, there is clearly a gap between the outer surface of the sleeve 38 and the inner surface of the lumen 20. The sleeve 38 is simply positioned over the steering wire 36 between the coil spring 48 and the tip electrode 19.

In response to the arguments above, the Office Action stated that “it is the examiner position that the stiffening member at the very least is attached to the glue (49), which is secured to the elongated body, and/or the stiffening member is secured to the electrode (19), which is secured to the elongate body.” [Office Action at page 4.] This position is respectfully traversed because there is no support whatsoever for it in the Webster patent. Simply being positioned next to something is not the same thing as being “secured to” something. ***In order to clarify the issues for appeal should the rejection be maintained, applicant hereby requests that the next Office Action:***

1. Specify precisely where, by column and line numbers, the Webster patent indicates that the steering wire sleeve 38 is “attached to the glue (49)” or is “secured to the electrode (19),” or

2. Provide an affidavit in accordance with MPEP § 2144.03 and 37 C.F.R. § 1.104(d)(2) that set forth the facts upon which the Examiner's conclusions regarding the Webster patent are based.

Finally, and referring to column 3, lines 34-37 and column 4, lines 18-35, it is also noteworthy that the Webster patent has this to say concerning the electrode 19, the puller wire 36, sleeve 38, the coil spring 48 and the glue 49:

In the embodiment shown, tip electrode 19 is **mounted** at the distal end of the tip portion 14 by means of tubular insert 21. It is understood that any suitable **attaching means** may be used.

A tightly wound coil spring 48 is disposed in the portion of the second lumen 20 which extends through the catheter body 12. The proximal and distal ends of the coil spring 48 are **fixed, e.g., by glue 49 or the like, to the wall** of the catheter body 12, forming the second lumen 20.

* * *

In the embodiment shown in FIG. 1, the coil spring 48 does not extend into the tip portion 14. **In the portion of the second lumen 20** which extends into the tip portion 14, there **is disposed** a flexible, compressible, and preferably lubricous sleeve 38, preferably made of polytetrafluoroethylene.

* * *

The distal end of the puller wire 36 is **fixedly attached to the tip electrode 19, e.g., by weld 31** or the like. Alternatively, the puller wire 36 may be **fixedly attached** to the outer wall of the tip portion 14.

[Emphasis added.] Thus, the Webster patent makes it perfectly clear when something is actually secured to something else by using words and phrases like "attaching means," "fixed, e.g., by glue," and "fixedly attached ... by [a] weld." No such words and phrases are used in connection with the sleeve 38. Instead, the Webster patent merely indicates that the sleeve 38 is "disposed" in a portion of the lumen 20.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 1, applicant respectfully submits that claims 1, 4, 5, 11, 17-19 and 26 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

D. Discussion Concerning Claim 2

Independent claim 2 calls for a combination of elements comprising “an elongate body defining ... a central lumen,” “a steering wire,” “a stiffening member associated with the distal portion of the elongate body,” “a stiffening member lumen offset from the central lumen, at least a portion of the stiffening member being located within the stiffening member lumen and the steering wire not being located within the stiffening member lumen” and “a handle.” The Webster patent fails to teach or suggest such a combination.

The Office Action has taken the position that because the phrase “‘stiffening member’ has very little structure ... , substantially anything within the Webster patent could be regarded as a stiffening member.” [Office Action at page 4.] Based on this position, the Office Action indicates that with respect to claim 2, one or more of the Webster lead wires 62 that carry current to the electrodes 15 and 19, correspond to the “stiffening member” because the lead wires 62 “have some amount of stiffness.”

In a recent *en banc* decision, the Federal Circuit reiterated that “[t]he Patent and Trademark Office (‘PTO’) determines the scope of the claims in patent applications not solely on the basis of the claim language, but upon giving the claims their **broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’**” *Phillips v. AWH Corp.*, 75 USPQ2d 1321, 1329, (Fed. Cir. 2005) (citations omitted, emphasis added). The interpretation of “stiffening member” set forth in the Office Action appears to encompass any structure of any kind so long as it is formed from a material that has some stiffness. This would include everything but gas. Applicant respectfully submits that this interpretation falls far short of the *Phillips* standard. The present specification describes a plethora of exemplary stiffening members. [See, e.g., Figure 6-10b and page 12, line 16 to page 16, line 18.] Although the claimed “stiffening member” is not limited to these examples, applicant respectfully submits that one of ordinary skill in the art who had read the specification would not read “stiffening member” so broadly that it corresponded to one or more tiny electrical lead wires.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 2, applicant respectfully submits that claim 2 is patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

E. Discussion Concerning Claims 20 and 21

Independent claim 20 calls for a combination of elements comprising “an elongate body,” “a steering wire,” “a stiffening member,” “an ***anchoring member*** located within the wall of the distal portion of the elongate body between the inner surface and the outer surface, ***in contact with the wall*** and ***secured to the distal portion of the steering wire and to the distal end of the stiffening member***” and “a handle.” The combination defined by claim 21 includes, *inter alia*, the elements recited in claim 20. The Webster patent fails to teach or suggest such combinations.

For example, the Office Action appears to have taken the position that, with respect to claim 20, the Webster weld 31 corresponds to the claimed “anchoring member” and the steering wire sleeve 38 corresponds to the claimed “stiffening member.” Even assuming for the sake of argument that this is a reasonable interpretation of claim 20, the weld 31 is in contact with the tip electrode 19, not the tip portion 12. [Column 4, lines 61-62.] Also, as illustrated in Figures 1 and 4, there is a structure (i.e. the steering wire sleeve 38 or the coil spring 51) between the weld 31 and the tip portion 12.

In response to the arguments above, the Office Action stated that column 4, lines 64 and 65 of the Webster patent “clearly indicate that the weld can be in contact with the outer wall of the elongate body.” [Office Action at page 5.] This statement is patently false. Column 4, lines 63-68 of the Webster patent mentions the use of an alternative to welding the puller wire 36 to the tip electrode 19, not using the weld 31 to secure the puller wire 36 to the catheter tip portion 12. The alternative is described in U.S. Patent No. 4,960,134 to Webster (“the Webster ‘134 patent”).

The Webster '134 patent discloses the use of a tube 32 and cross-piece 33 to secure a puller wire 30 to catheter tip portion 12. The puller wire 30 is surrounded by a steering wire sheath 31. The distal end of the steering wire sheath 31 is not secured to the tube 32. [Note the gap therebetween in Figure 3 of the Webster '134 patent.] Accordingly, even if the tube 32 and cross-piece 33 arrangement was used to secure the puller wire 36 to the tip portion 12 in the cited Webster patent, and could be considered an "anchoring member," the claimed combination would not be anticipated because the distal end of the steering wire sleeve 38 (i.e. the purported "stiffening member") would not be secured to the tube 32.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 20, applicant respectfully submits that claims 20 and 21 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

F. Discussion Concerning Claims 24 and 43-46

Independent claim 24 calls for a combination of elements comprising, *inter alia*, "an anchoring member," "a stiffening member ... **defining a distal end, the distal end of the stiffening member being directly secured to the anchoring member**" and "an anti-tear device configured and positioned relative to the stiffening member so as to prevent the stiffening member from tearing through the elongate body when the stiffening member bends." The combinations defined by claims 43-46 include, *inter alia*, the elements recited in claim 24. The Webster patent fails to teach or suggest such combinations.

For example, the Office Action has taken the position that, with respect to independent claim 24, the Webster tip member 19 corresponds to the claimed "anchoring member," the coil spring 48 and/or the steering wire sleeve 38 corresponds to the claimed "stiffening member," and the ring electrodes 15 and glue 49 corresponds to the claimed "anti-tear device." [Office Action at page 3.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, there is nothing in the

Webster patent that even remotely indicates that the **distal ends** of the coil spring 48 or the sleeve 38 are **directly secured to** the tip member 19. The coil spring 48 is secured to the tip portion 14, not to the tip member 19, and the sleeve 38 is not secured to anything.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 24, applicant respectfully submits that claims 24 and 43-46 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

G. Discussion Concerning Claim 25

Independent claim 25 calls for a combination of elements comprising, *inter alia*, “an anchoring member,” “an anti-tear device,” and “a stiffening member associated with the distal portion of the elongate body and defining a distal end, **the distal end of the stiffening member being directly secured to the anchoring member**, and a proximal end secured to the anti-tear device.” The Webster patent fails to teach or suggest such combinations.

For example, the Office Action has taken the position that, with respect to independent claim 25, the Webster tip member 19 corresponds to the claimed “anchoring member” and the coil spring 48/51 corresponds to the claimed “stiffening member.” [Office Action at page 4.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, there is nothing in the Webster patent that even remotely indicates that the **distal end** of the coil spring 48/51 is **directly secured to** the tip member 19. Referring to Figure 4, which shows the version with the loosely wound spring distal portion 51 in place of the steering wire sleeve 38, the glue 49 secures the distal end of the tightly wound spring portion 48 to the tip portion 14. Although the spring distal portion 51 abuts the tip member 19, the Webster patent does not indicate that it is secured thereto.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 25, applicant respectfully submits that claim

25 is patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

H. Discussion Concerning Claim 47, 48, 50 and 51

Independent claim 47 calls for a combination of elements comprising, *inter alia*, “a stiffening member associated with the distal portion of the elongate body” and “an anti-tear device positioned adjacent to at least a portion of the stiffening member and ***configured to prevent the stiffening member from tearing through the elongate body when the stiffening member bends.***” The combinations defined by claims 48, 50 and 51 include, *inter alia*, the elements recited in claim 47. The Webster patent fails to teach or suggest such combinations.

For example, the Office Action has taken the position that, with respect to independent claim 47, the Webster tubular insert 21 corresponds to the claimed “stiffening member” and that “attachment means” corresponds to the claimed “anti-tear device.” Although it is not entirely clear what the Office Action is referring to by “attachment means,” applicant has assumed for the purposes of this response that the Office Action is referring to the “attaching means” mentioned to in column 3, lines 34-38.² Column 3, lines 34-38 of the Webster patent is reproduced below.

In the embodiment shown, tip electrode 19 is mounted at the distal end of the tip portion 14 by means of tubular insert 21. It is understood that any suitable attaching means may be used.

The above-quoted passage appears to be referring to “any suitable attaching means” as an alternative to the tubular insert 21 in the illustrated embodiment. As such, the Webster catheter would not include both the tubular insert 21 and the “attaching means.” It would be one or the other. Nevertheless, to the extent that the Office Action has taken the position that the “attaching means” is something that secures the tubular insert 21 to both the tip portion 14 and tip electrode 19, applicant notes that “[a] rejection

² Should applicant’s assumption be incorrect, applicant hereby requests that the next Office Action indicate, by reference numeral and/or column and line number, exactly what aspect of the Webster device purportedly corresponds to the claimed “anti-tear device” in order to clarify the issues for appeal.

for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. In addition, the reference ***must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill*** in the field of the invention.” *In re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (citations omitted, emphasis added). The phrase “any suitable attaching means” does not describe an “anti-tear device ... configured to prevent the stiffening member from tearing through the elongate body when the stiffening member bends,” as this phrase would be understood by a person of skill in the art who had reviewed the specification, sufficiently to place it in the possession of a person of ordinary skill in the art.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 47, applicant respectfully submits that claims 47, 48, 50 and 51 are patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

Additionally, in order to clarify the issues for appeal in the event that the rejection is maintained, applicant hereby requests that the next Office Action indicate which of the two possible interpretations of column 3, lines 34-38 forms the basis for the rejection.

I. Discussion Concerning Claim 64

1. Legal and Procedural Issues

The Office Action states that “[i]t is interesting that applicant failed to use all of the words used in the MPEP to describe how the means plus function should be interpreted. That word is ‘equivalence.’” [Office Action at page 5.] This “interesting” statement, which was in response to applicant’s arguments concerning the failure of a prior art element to perform the function recited in a means-plus-function element, demonstrates a fundamental lack of understanding concerning the manner in which means-plus-function elements are evaluated. The MPEP requires a ***two-part analysis*** of means-plus-function elements. ***First***, “the application of a prior art reference to a means or step plus

function limitation **requires** that the prior art element **perform the identical function** specified in the claim.” [MPEP § 2182, emphasis added.] **Second**, “**if a prior art reference teaches identity of function** to that specified in a claim, **then** under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.” [Id., emphasis added.] Accordingly, if the prior art element does not perform the claimed function, the issue of whether or not the prior art element is an equivalent is not “interesting,” it is irrelevant.

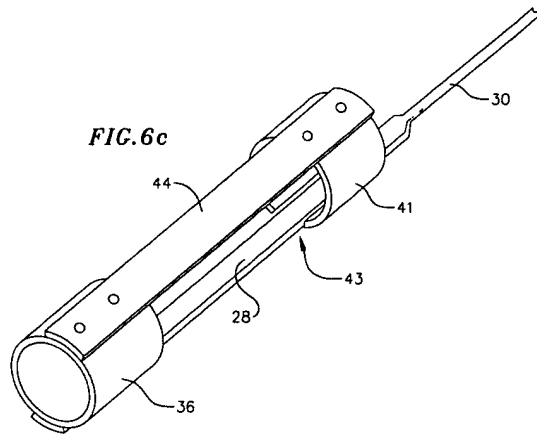
It is also noteworthy that, with respect to the “interesting” issue of “equivalence,” MPEP § 2183 indicates that if the examiner finds that the prior art element performs the function specified in the claim and is an equivalent, then “the examiner should provide an explanation and rationale in the Office Action as to why the prior art element is an equivalent.” MPEP § 2183 even provides a useful list of factors to aid in this analysis. Unfortunately, the Office Action’s explanation and rationale consisted of “[b]ased on applicant’s vague specification, the glue meets all of the requirements of the means plus function set forth in the MPEP.” [Office Action at page 5.]

The Office Action’s explanation and rationale is deficient for at least two reasons. First, with respect to vagueness, applicant notes that one of skill in the art who had read the specification, prior to the amendment above, would have come upon the following:

Referring to FIGURE 6c, the distal end of a stiffening member, such as stiffening member 44 (described below), may be secured to the anchoring member 36 and an **anti-tear device 41** may be secured to the proximal end of the stiffening member. The **anti-tear device 41**, which is located within the elongate body distal portion 24a and which includes a slot 43 through which the steering wire distal portion 28 passes, **spreads the forces associated with the bending of the stiffening member 44 over a greater surface area, thereby preventing the bending member from tearing through the elongate body distal portion. A suitable anti-tear device may be constructed by forming the slot 43 in a hypotube.**

[Specification at page 13, lines 4-12.] One of skill in the art would have been able to readily associate the words “anti-tear device” with the words “anti-tear means.” One of skill in the art would also have been able to read and understand functional phrases like

“spreads the forces associated with the bending of the stiffening member 44 over a greater surface area” and “preventing the bending member from tearing through the



elongate body distal portion.” One of skill in the art would have also noticed that the application includes an illustration of the structure that performs this function, i.e. anti-tear device 41 illustrated in Figure 6c, as well as a suitable method of construction, i.e. forming the slot 43 in a hypotube. Accordingly, one of skill in the art would have found that the application, as filed, provided

enough information for the “anti-tear means” to be evaluated in accordance with MPEP § 2183.

Turning to the second reason that the Office Action’s explanation and rationale is deficient, it is devoid of anything (such as the factors discussed in MPEP § 2183) that would support the conclusion that glue is the equivalent of the structure disclosed for performing the claimed function, i.e. the anti-tear device 41. In order to clarify the issues for appeal should the rejection be maintained, applicant hereby requests that the next Office Action include the equivalence and rationale analysis called for in MPEP § 2183.

2. Factual Issues

Independent claim 64 calls for a combination of elements comprising, *inter alia*, “a stiffening member associated with the distal portion of the elongate body such that the stiffening member will apply a force over an elongate body surface area when the stiffening member is bent” and “***anti-tear means***, associated with the stiffening member, ***for increasing the elongate body surface area over which the force is applied when the stiffening member is bent to prevent the stiffening member from tearing through the elongate body.***” The Webster patent fails to teach or suggest such a combination.

For example, the Office Action appears to have taken the position that, with respect to claim 64, the Webster steering wire sleeve 38 and/or coil spring 48 corresponds to the “stiffening member” and that the glue 49 corresponds to the “anti-tear means.” [Office Action at pages 3 and 5.] In other words, the Office Action has taken the position that (1) the glue 49 prevents the sleeve 38 from tearing through the tip portion 14 or (2) the glue 49 prevents both the sleeve 38 and the coil spring 48 from tearing through the catheter body 12 and tip portion 14 or (3) the glue 49 prevents the coil spring from tearing through the catheter body 12.

With respect to options (1) and (2), which involve the steering wire sleeve 38, there is nothing in the Webster patent itself which even remotely suggests that the glue 49, which is actually used to secure the coil spring 48 to the catheter body 12, performs the function recited in the claimed means-plus-function element as it would related to the sleeve 38. In fact, there is nothing in the Webster patent which even indicates that the glue 49 is adhered to, or otherwise interacts with, the sleeve 38.

In response to arguments similar to those above, the Office Action indicated that “[u]nfortunately, figs. 1 and 4 clearly discloses and describes the interaction between the two.” [Office Action at page 5.] Figure 1 merely shows that the sleeve 38 is located next to, and distal of, the glue 49. [See also, Section III-C above.] “Unfortunately,” the device illustrated in Figure 4 does not even include the sleeve 38.

Turning to option (3), the only function that the Webster patent actually discloses for the glue 49 is securing the coil spring 48 to the catheter body 12. The Webster patent does not indicate that the glue 49 performs the function of preventing the coil spring 48 from tearing through the catheter body 12.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 64, applicant respectfully submits that claim 64 is patentable thereover and that the rejection thereof under 35 U.S.C. § 102 should be withdrawn.

IV. NEWLY PRESENTED CLAIMS 66-68

Newly presented claim 66 depends from independent claim 24 and, accordingly, is patentable for at least the same reasons as claim 24.

Newly presented claims 67 and 68 depend from independent claim 64 and, accordingly, is patentable for at least the same reasons as claim 64.

V. CLOSING REMARKS

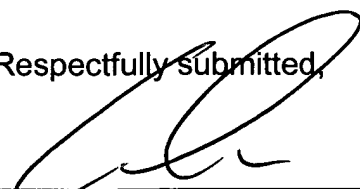
In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

11/21/05
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